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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,767	02/10/2004	Lester Earl Casida JR.	8014-020-999	3630

20583 7590 02/05/2007

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,767	CASIDA ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-85* is/are pending in the application.

4a) Of the above claim(s) *78,79 and 81-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *68-77 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/10/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I and the species of "living whole cells" in the reply filed on 11/03/2006 is acknowledged. The traversal is on the ground(s) that there is no serious burden in searching and examining all claims. This is not found persuasive because different groups of claims and different species are drawn to products and methods having different scope as claimed and, thus, the references that would be applied to one group of claims would not necessarily anticipate or render obvious the other group(s). Moreover, as to the question of burden of search, classification of subject matter is also an indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group. For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 78, 79 and 81-85 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction/election requirement in the reply filed on 11/03/2006.

Claims 68-77 and 80 are under examination in the instant office action.

Claim Rejections - 35 USC § 112

Written description

Claims 68-77 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are directed to a method for treating or inhibiting a disease of an animal, said disease caused by a microorganism wherein the method comprises administering to said animal an effective amount of an antimicrobial preparation comprising living cells of *Burkholderia casidae* or variant thereof wherein the *Burkholderia casidae* or variant thereof.

The limitation "an effective amount" of *Burkholderia casidae* or variant thereof in the method for *in vivo* treating or inhibiting diseases of animals or humans lacks support in the instant specification. This limitation is neither has literal support in the as-filed specification by way of a generic disclosure, nor are there specific examples of using the applicants' *Burkholderia casidae* or variant thereof in the method for *in vivo* treating or inhibiting a disease of an animal or a human that would show possession of the concept of the use of any and all "effective amount(s)" for any and all infections listed in claims 70-73. There is only a generic phrase that *Burkholderia casidae* may be used in the prevention and/or treatment of microbial diseases of animals (page 4, last line) including humans (page 5, line 3). However, the specification does not even describe those bacteria, yeasts, fungi or alga that are considered as causing diseases of animals not plants. In fact, some the claimed infections are plant pathogens,

for example: *Alternaria, Botrytis*, etc. Thus, one skilled in the art cannot visualize or recognize the effective amounts *Burkholderia casidae* of treating various infections including that are claimed in animals or humans.

Given the total lack of any description of "effective" amounts for *Burkholderia casidae* or variant thereof in the method for *in vivo* treating or inhibiting a disease of an animal or a human, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Enablement

Claims 68-77 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are directed to a method for treating or inhibiting a disease of an animal, said disease caused by a microorganism wherein the method comprises administering to said animal an effective amount of an antimicrobial preparation comprising living cells of *Burkholderia casidae* or variant thereof wherein the *Burkholderia casidae* or variant thereof.

The claimed *Burkholderia casidae* or variant thereof has a 16S rRNA gene comprising a sequence that is at least 97% similar to the sequence of SEQ ID NO: 1 and characterized by a particular cellular fatty acid composition. Some claims are further drawn to the used of a particular strain 2.2N (ATCC 55961).

Some claims are further drawn to the antimicrobial activity against bacteria including *Agromyces, Arthrobacter, Micrococcus luteus, Mycobacterium, Nocardia, Staphylococcus aureus or Streptomyces*, to the antimicrobial activity against yeasts including *Saccharomyces cerevisiae, Candida albicans or Cryptococcus neoformans*; to the antimicrobial activity against fungi including *Alternaria, Aspergillus niger, Botrytis cinerea, Cercospora, Cercosporidium, Geotrichum, Mycosphaerella, Mucor, Penicillium, Phoma, Phytophthora, Plasmopora, Pseudopeziza, Puccinia, Pythium, Rhizoctonia, Rhizopus, Septoria nodorum, Sporothrix, Stemphylium, Trichophyton or Verticillium*; to the antimicrobial activity against alga such as is *Anabena.*

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The breadth of the claims are drawn to the use of *Burkholderia casidae* as a probiotic or to the use of whole living cells of *Burkholderia casidae* or variant thereof including strain ATCC 55961 for *in vivo* administration to animals including humans. The claimed bacteria is a novel strain as established in the parent application (now US 6,319,497) and it is used for treating plant diseases (US 6,689,357).

However, the instant specification does not support the scope of the claims drawn to the use of living cells of *Burkholderia casidae* or variant thereof including strain ATCC 55961 for *in vivo* administration to animals including humans as intended for treating and inhibiting microbial infection. The "effective" amounts for in vivo administration and *in vivo* treating or inhibiting microbial infections in animals or humans are not disclosed in the specification by way of generic disclosure or in the working examples. The applicants' working examples are only limited to the *in vitro* testing of *in vitro* antimicrobial activities of the claimed bacteria on agar plates.

The state of the prior art demonstrates that some bacteria belonging to the claimed genus of *Burkholderia* including species of *B.cepacia* that is closely related to the applicants' strain (se specification table 3, page 25) have been reported as opportunistic human pathogens, they were isolated from clinical specimens of diseased patients and some of them were associated with cystic fibrosis, for example: see introduction of the reference by Tabacchioni et al. (IDS reference; Res. Microbiol. 1995, 146, 531-542). The applicants' novel strain has been isolated from soil (specification page 16, lines 20). However, the reference by Tabacchioni et al. teaches that some human pathogens can be isolated from soil or from the same ecological niche as the plant-growth promoting bacteria (page 532, col.1, lines 6-9) and that screening for potential pathogenicity of soil isolates would be needed. The instant applicants does not describe any testing that would involve animal or human models. Thus, the claimed concept of using the applicants' novel strain of *Burkholderia casidae* for in vivo administration for treating diseases is uncertain and unpredictable in the absence of at least some potential pathogenicity testing.

Further, in alternative, even if the applicants' novel strain of *Burkholderia casidae* might not be an animal or human potential pathogen, the fact that it was isolated from soil clearly demonstrates that this strain is not a normal inhabitant of animals or humans. The state of prior art teaches the characteristics of a good probiotic fro treating animal or human infections such as being a normal inhabitant of the site of application, capable of surviving and growing in the site of application, capable to exert beneficial effects on the host, etc., for example: see page 312 of the reference by O'Sullivan et al. (Trends in Food and Technology. 1992, vol. 3, page 309-314). The instant application is silent about ability of the claimed *Burkholderia casidae* to adhere, to survive, to colonize and to grow on animal or humans tissues *in vitro* and/or at the site of *in vivo* applications. No animal or human model is shown by applicant to support enablement of the claimed concept of treating or inhibiting undesirable microorganisms in the animals or humans including inhibiting the bacteria, yeast, fungi and alga that are listed in the instant claims 70-73.

Therefore, neither specification nor the prior art can be said to support the enablement of the claims over their breath.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and absence of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art. Without sufficient guidance administration of the applicants' strain as currently claimed is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. As set forth in *In re Fisher*, 427 F2.d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section

112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.
In cases involving unpredictable factors, such as in vivo physiological activity of therapeutic agent, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. *Ex parte Humphreys*, 24 USPQ2d, 1260.

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

February 1, 2007

V. Afremova

VERA AFREMOVA

PRIMARY EXAMINER